BPOG February Newsletter

Hello,

The New Year is already This Year. We hope it started well for you! New BPOG meetings are confirmed for March and April. New members are announced along with some new facilitators on our team. Enjoy the read.

Regards

Simon Chalk

Formulation paper supporting harmonization of drug product robustness studies

As part of the BPDG Formulation Point Share activities, an intercompany collaboration exercise was performed that included a bench-marking survey and extensive group discussions around the scope, design, and execution of biopharmaceutical drug product robustness studies. The Point Share has now published key common themes as "An Intercompany Perspective on Biopharmaceutical Drug Product Robustness Studies" in the Journal of Pharmaceutical Sciences. It is hoped that the paper will have a significant impact on harmonizing biopharmaceutical development practices.

BPOG leading industry approaches at BPI West

If you are heading to BioProcess International West in March you will probably be aware that Reed Harris, Technical Development Senior Staff Scientist, Global Technical Development (PTD), Genentech, is delivering a talk on BPOG’s Technology Roadmapping process. The creation of the first edition Biomanufacturing Technology Roadmap has quickly led to the implementation of several projects that will provide the step change required to address key future innovation challenges identified by the member organizations.

Data Integrity and Agile Webinars to support industry response to regulators

The BPIT Compliance workstream has published an industry response to the IT Data Integrity guidelines provided by regulators. This is an area that has been a major focus for inspectors in recent times.

The guidance and supporting template provides clarity and agreement of the regulatory requirements, a shared view of which controls to implement within a company, and offers best practices. This results in a common response to regulators and achieves increased confidence in companies' approach to compliance.

New Members

We are pleased to welcome the following new members into the BPOG collaboration at the start of 2018. We have seen new member companies join BPOG as a whole, companies returning to Phorums and those members who are extending their involvement across multiple Phorums. It gives the Phorums a great start to the year to share knowledge and experience within workstreams for what is a busy year of face-to-face meetings ahead and combined with a significant increase in deliverables across the board.
Colder Products have joined both Supply Partner Phorum and Technology Roadmapping. Siemens is also welcomed as new member to Technology Roadmapping. Friesland Campina are welcomed to the Supply Partner Phorum

Development Group have continued their growth at the end of 2017 and are now joined by Samsung.

BPIT can announce that Lonza have joined the Phorum and are looking forward to expanding their membership throughout the first quarter of 2018.

CSL Behring has joined the Fill Finish Phorum and Astra Zeneca have re-joined the Drug Substance Phorum.

Cook Pharmica, members of both Drug Substance and Fill Finish, have been acquired by Catalent who will continue their BPOG Membership, with a view to extending value into the wider Catalent organization in the future.

---

**New Facilitators**

Isabelle Lequeux has joined the Drug Substance Phorum as a facilitator, coming to us after a successful career in GSK as a Principal Scientist. Despite years working in the UK, she is still resoundingly Gallic and doubles the numbers of French nationals in our team, to Christelle's great delight. Her first assignment will be with the Post Approvals Submissions team, to help them widen their reach into other health authorities having proved how influential they can be with ANVISA in the last year.

Alison Wilson joined the Fill Finish team in January having previously been a Production Director in BTG's aseptic operations. She is already getting stuck in, mobilizing our new Pre-Use Post Sterilization Integrity Test (PUPSIT) team as they work out how to address the challenges posed by the recent Annex 1 release. Those attending the 17th Fill Finish meeting will meet Alison in Athlone in March 2018, or if you are on the PUPSIT team then you will work with her in Bethesda in April, 2018.

Finally, Steve Nicoll joins the Supply Partner Phorum team after a career in Rupert Murdoch's News International, where, during the late 80s and 90s he was one of the leaders who drove the technology and employment changes that revolutionized the UK newsprint industry. Now, after a short stint leading change in PharmaCo, we can benefit from his experience as we support a similar revolution in our supply chains. If you get to work with Steve, corner him at the bar, we're sure he has some fascinating stories to share.

---

**Upcoming Face-to-Face Meetings:**

Storage and Transport 02 (Drug Substance) - 6-8 March 2018, Copenhagen, Denmark - to engage suppliers and, refine best practice lane and equipment qualification process.

Single Use User Requirements 05 (Drug Substance) - 6-8 March 2018, Seattle, Washington State, USA - this meeting will finalize the structure and content of the workstream deliverables in readiness for launching the implementation of the Single Use User Requirements deliverables.

Container Closure Integrity Testing 05 (Fill Finish) - 6-8 March 2018, Basel, Switzerland - to develop the Container Closure Integrity Testing Technology Roadmap.

Development Group Core Team Meeting 22 (Development Group) - 13-15 March 2018, Boston, Massachusetts, USA - to discuss process intensification, new technologies and continuous manufacturing.

Disposables Change Notification 05 (Drug Substance) - 13-15 March 2018, Oakland, California, USA - to look at implementation status, CoP development, training roadshow.

Lean Qualification and Validation 01 (Drug Substance) - 13-15 March 2018, London, UK - preparing the workstream for planning and implementation stages with defined benefits, acceptance criteria, fully defined deliverables and detailed plans for their implementation.

Supply Chain Visibility (BPIT) - 20-22 March 2018, New Jersey, USA - develop the common industry model for LSP integration and produce the requirements specification.

Fill Finish Core Team Meeting 17 (Fill Finish) - 20-22 March 2018, Athlone, Ireland - explore isolator filler best practices.
Extractables and Leachables 03 (Drug Substance) - 10-12 April 2018, Cambridge, Massachusetts, USA - to look at the community of practice and supplier collaboration.

Pre-Use Post Sterilization Integrity Test 01 (Fill Finish) - 10-11 April 2018, Washington DC, USA - launch the PDA/BPOG PUPSIT program. Plan out the approach to the masking study and PUPSIT best practice work.

Industry Capacity Constraints Analysis 02 (Supply Partner Phorum) - 12-13 April 2018, Research Triangle Park, Raleigh/Durham, North Carolina, USA - to provide an assessment of global manufacturing capacity of aggregated raw material consumption, analyze the data to assess what, if any, constraints may apply in anticipated industry capacity growth.

Forecasting and Demand 02 (Supply Partner Phorum) - 17-18 April 2018, Charleston, North Carolina, USA - to create a pathway to implementation, change, and value realization within supply chain forecasting and promote our Best Practice Guide.

Compliance 03 (Information Technology) - 18-19 April 2018, Baltimore, Maryland, USA - develop the value propositions, plans, approaches and deliverables for the Agile playbook and Compliant MultiSource Analytics. Additionally, to shape Data Integrity Framework’s for Vendors and CMO’s for 2018 kick off decision.

Small Flexible Fillers 01 (Fill Finish) - 18 April 2018, New York, USA - launch of small flexible filler URS with suppliers alongside INTERFEX.

Microbial Control 02 (Drug Substance) - 24-26 April 2018, Leiden, Netherlands - detailed planning and group work to progress the Microbial Control five year plan.

Supply Base Reliability (Drug Substance) - 24-26 April 2018, Oakland, California, USA - this meeting will formally see the launch and detailed planning of the workstream.

Drug Substance Core Team Meeting 31 (Drug Substance) - 24-22 May 2018, Cork, Ireland - focus on co-implementation of single use user requirements, change notification, raw materials variability, and consideration of strategic new topics through review of the Technology Roadmap and other external stimulus.

Technology Roadmapping Steering Committee Meeting 07 (Technology Roadmapping) - 23-24 May 2018, Philadelphia, USA - steering committee meeting to review overall program. Plan strategy for publishing second edition roadmap plus a review of current projects and decisions.